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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,414	06/27/2001	Mark E Gurney	29915/6280M	2436

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/869,414	Applicant(s) GURNEY ET AL.	
	Examiner Christopher Nichols, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-150 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-23 and 139-140, drawn to a method for producing a polypeptide comprising SEQ ID NO: 63 comprising polynucleotide, vectors, and host cells comprising same.

Group 2, claim(s) 26-28, 29-35, and 142 (each in part), drawn to a method for producing a polypeptide comprising SEQ ID NO: 7 comprising polynucleotide, vectors, and host cells comprising same, and the polypeptide comprising SEQ ID NO: 7.

Group 3, claim(s) 24-25, 38-46, and 141-142 (each in part), drawn to a method for producing a polypeptide comprising SEQ ID NO: 8 comprising polynucleotide, vectors, and host cells comprising same, and the polypeptide comprising SEQ ID NO: 8.

Group 4, claim(s) 47-54, 58-60, 62-70, and 142 (each in part), drawn to a method for producing a polypeptide comprising SEQ ID NO: 4 comprising polynucleotide, vectors, and host cells comprising same, and the polypeptide comprising SEQ ID NO: 4.

Group 5, claim(s) 47-48, 55-57, 61-64, 71-82, and 142 (each in part), drawn to a method for producing a polypeptide comprising SEQ ID NO: 6 comprising polynucleotide, vectors, and host cells comprising same, and the polypeptide comprising SEQ ID NO: 6.

Group 6, claim(s) 83-87, 89-95, 143, 147 a method for assaying for modulators of  $\beta$ -secretase activity wherein the substrate polypeptide of the second composition comprises SEQ ID NO: 63.

Group 7, claim(s) 83-86, 88-95, 143 a method for assaying for modulators of  $\beta$ -secretase activity wherein the substrate polypeptide of the second composition comprises SEQ ID NO: 67.

Group 8, claim(s) 96 and 97, drawn to a method of identifying agents that inhibit the activity of human Asp2 aspartyl protease (Hu-Asp2).

Group 9, claim(s) 98-102, drawn to a method involving nucleotide sequences.

Group 10, claim(s) 103, 107, 120, and 123 drawn to a method for treating Alzheimer's disease.

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Group 11, claim(s) 104-106, 108-119, 124-129, 144-146, and 148-150 drawn to a method for identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2).

Group 12, claim(s) 121-122, drawn to a method for identifying agents that **modulate** the activity of human Asp2 aspartyl protease (Hu-Asp2).

Group 13, claim(s) 130-137, drawn to a method of reducing cellular production of amyloid beta from amyloid precursor protein using an anti-sense reagent.

Group 14, claim(s) 138, drawn to a method of diagnosing Alzheimer's disease.

4. The inventions listed as Groups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

5. Group 1 recites the technical features of SEQ ID NO: 63, which is not required by the other Groups.

6. Group 2 recites the technical features of SEQ ID NO: 7, which is not required by the other Groups.

7. Group 3 recites the technical features of SEQ ID NO: 8, which is not required by the other Groups.

8. Group 4 recites the technical features of SEQ ID NO: 4, which is not required by the other Groups.

9. Group 5 recites the technical features of SEQ ID NO: 6, which is not required by the other Groups.

10. Group 6 recites the technical features of a method for assaying for modulators of  $\beta$ -secretase activity wherein the substrate polypeptide comprises SEQ ID NO: 63, which is not required by the other Groups.

11. Group 7 recites the technical features of a method for assaying for modulators of  $\beta$ -secretase activity wherein the substrate polypeptide comprises SEQ ID NO: 67, which is not required by the other Groups.

12. Group 8 recites the technical features of a method of identifying agents that inhibit the activity of Hu-Asp2, which is not required by the other Groups.

13. Group 9 recites the technical features of a method involving nucleotide sequences, which is not required by the other Groups.

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14. Group 10 recites the technical features of a method of treating Alzheimer's disease, which is not required by the other Groups.

15. Group 11 recites the technical features of a method for identifying agents that inhibit the activity of Hu-Asp2, which is not required by the other Groups.

16. Group 12 recites the technical features of a method for identifying agents that modulate the activity of Hu-Asp2, which is not required by the other Groups.

17. Group 13 recites the technical features of a method of reducing cellular production of amyloid beta from amyloid precursor protein using an anti-sense reagent, which is not required by the other Groups.

18. Group 14 recites the technical features of a method of diagnosing Alzheimer's disease, which is not required by the other Groups.

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher James Nichols, Ph.D. whose telephone number is (703) 305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Elizabeth C. Hummer*

CJN  
February 21<sup>st</sup>, 2003